

## caBIG CTMS Best Practice SIG – SOP WG

The following is a **prioritized list of SOPs** and accompanying documentation which the SOP Working Group will be initially focusing on. The table also lists the SOP WG Meeting date on which the SOP will be presented for review. The priority is based on a need for procedures to facilitate closing studies currently in progress.

| SOP    | SOP Title   | SOP WG Meeting    |
|--------|---|-------------------|
| CR-008 | Study Close SOP   | November 29, 2005 |
| AD-006 | Revoking of Patient consent under HIPAA SOP                     | November 29, 2005 |
| CR-009 | Clinical Data Management Plan Guideline                         | November 29, 2005 |
| CR-010 | Data Safety Monitoring Board Review (DSMB) SOP                  | December 13, 2005 |
| CR-011 | Breaking the Statistical Blind SOP                              | December 13, 2005 |
| CR-012 | Study Reports (ISS & ISE formats) SOP                           | January 24, 2006  |
| AD-007 | Training Process (on implementing SOPs training using CBT) SOPs | January 24, 2006  |
| CR-013 | Statistical Analysis Plan SOP                                   | January 24, 2006  |
| CR-014 | Patient Registration (C3PR) SOPs                                | January 24, 2006  |
| CR-015 | Dictionary Maintenance SOP                                      | February 28, 2006 |
| IT-006 | Data Export/Import SOP  | February 28, 2006 |
| CR-016 | Protocol Administration (C3PA) SOP                              | February 28, 2006 |
| AD-008 | Change Control (systems) SOP                                    | March 28, 2006    |
| CV-002 | Computer Systems Validation SOP                                 | March 28, 2006    |

As a reminder, the following SOPs have been developed and issued:

- SOP for Developing and Maintaining SOPs
- SOP for Revisions and Deviations of SOPs
- SOP for Release and Distribution of SOPs
- SOP for Security Compliance (HIPAA)
- SOP for Patient Privacy (HIPAA)
- SOP for Study Setup
- SOP for Study Conduct
- SOP for CRF
- SOP for CDE Curation
- SOP for Application Standards Library Maintenance
- SOP for Coding of Data
- SOP for Reconciliation of Serious Adverse Event Database
- SOP for 21 CFR Part 11 Compliance
- SOP for Establishing and Maintaining User Accounts
- SOP for Retiring User Accounts
- SOP for Electronic Loading of Lab Data
- SOP for Electronic Loading of CDEs
- SOP for Standard Programming